Listing of Claims

1-34 (cancelled)

35. (original) A stable pharmaceutical formulation comprising:

    a) a GLP-1 compound selected from the group consisting of: GLP-1, GLP-1 analogs, and GLP-1 derivatives wherein the GLP-1 compound can bind to the GLP-1 receptor;

    b) a tween polymeric surfactant;

    c) a preservative; and

    d) a buffer

    wherein the stable formulation is a solution and has a pH between about 6.5 and about 9.0.

36. (original) The formulation of Claim 35, wherein the GLP-1 compound is protected from the activity of dipeptidyl-peptidase IV.

37. (original) The formulation of Claim 35, wherein the GLP-1 compound comprises the sequence of SEQ ID NO:1 or SEQ ID NO:4.

38. (original) The formulation of Claim 36 wherein the GLP-1 compound comprises the sequence of SEQ ID NO:5.

39. (previously presented) The formulation of Claim 35 wherein the GLP-1 compound is GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), or the amide forms thereof, with at least one modification selected from the group consisting of:

    (a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;

    (b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;

    (c) substitution according to at least one of:

    Y for V at position 16;

    K for S at position 18;

    D for E at position 21;

S for G at position 22;

R for Q at position 23;

R for A at position 24; and

Q for K at position 26;

(d) substitution comprising at least one of:

glycine, serine, or cysteine for alanine at position 8;

aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;

serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and

glutamic acid for aspartic acid at position 15; and

(e) substitution of glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.

40. (original) The formulation of Claim 39, wherein the GLP-1 analog is acylated at an amino acid side group.

41. (original) The formulation of Claim 40, wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.

42. (original) The formulation of Claim 41, wherein the lysine that is acylated is lysine 34.

43. (original) The formulation of Claim 42, wherein the epsilon-amino group of lysine is acylated with an acyl group selected from the group consisting of C_6-C_{10} unbranched acyl.

44. (previously presented) The formulation of Claim 35 wherein the GLP-1 compound is a GLP-1 derivative prepared by the process of acylating a GLP-1 analog selected from the group consisting of GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), and the amide forms thereof, with at least one modification selected from the group consisting of:

(a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or

position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;

(b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;

(c) substitution according to at least one of:
Y for V at position 16;
K for S at position 18;
D for E at position 21;
S for G at position 22;
R for Q at position 23;
R for A at position 24; and
Q for K at position 26;

(d) substitution comprising at least one of:
glycine, serine, or cysteine for alanine at position 8;
aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;
serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and
glutamic acid for aspartic acid at position 15; and

(e) substitution of glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.

45. (original) The formulation of Claim 44 wherein the GLP-1 analog has an arginine substituted for lysine at position 34.

46. (original) The formulation of Claim 45 wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.

47. (original) The formulation of Claim 35, wherein the GLP-1 compound is a GLP-1 derivative.

48. (original) The formulation of Claim 35 further comprising an isotonicity agent.

49. (original) The formulation of Claim 48 wherein the isotonicity agent is glycerin.
50. (original) The formulation of Claim 48 wherein the isotonicity agent is sodium chloride.
51. (original) The formulation of Claim 35 further wherein the preservative is phenol.
52. (original) The formulation of Claim 35 further wherein the preservative is m-cresol.
53. (currently amended) A method of treating a person having a condition wherein said condition is characterized by elevated glucose levels, ~~by for which administration of a GLP-1 compound to patients with elevated glucose levels,~~ said method comprising administering a pharmacologically effective amount of a formulation of Claim 35.
54. (currently amended) The method of claim 53 wherein the condition is Type II diabetes.